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January 12, 2007

David Saliwanchik

David R. Saliwanchik, Patent Attorney

INFORMATION DISCLOSURE  
STATEMENT  
Patent Application  
Docket No. GJE-7462CXC1  
Serial No. 10/578,692

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : *Not yet assigned*

Applicant(s) : Rajiv Nayar, Mark Manning, Philip J. Barr, Philip A. Pemberton, Ian C. Bathurst,  
Helen Gibson

Serial No. : 10/578,692

Filed : May 10, 2006

For : Dry Recombinant Human Alpha 1-Antitrypsin Formulation

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

The above-identified patent application was filed in the U.S. Patent Office as a national application under 35 USC §371. A copy of the International Search Report and copies of the references cited therein have been made available in the national stage file.

However, for the examiner's convenience, the applicants are attaching a copy of the International Search Report as well as copies of the documents cited in the International Search Report. Also attached is Form PTO/SB/08 listing the references.

In accordance with 37 CFR §1.56, the applicants hereby request that the references cited in the International Search Report and listed on the attached form PTO/SB/08 be made of record and considered in the examination of the subject application. If any additional fee is required, or to credit any overpayment, please use Deposit Account No. 19-0065.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

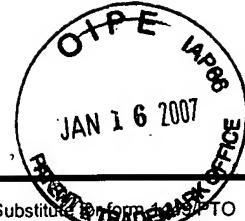
Respectfully submitted,



David R. Saliwanchik  
Patent Attorney  
Registration No. 31,794  
Phone No.: 352-375-8100  
Fax No.: 352-372-5800  
Address: P.O. Box 142950  
Gainesville, FL 32614-2950

DRS/wrc

Attachments: Form PTO/SB/08 (2 pages)  
International Search Report  
Copies of references cited (5)



Substitute Form 1470, USPTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

2

### Complete if Known

Application Number	10/578,692
Filing Date	May 10, 2006
First Named Inventor	Rajiv Nayar
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	GJE-7462CXC1

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
U1	US-				
U2	US-				
U3	US-				
U4	US-				
U5	US-				
U6	US-				
U7	US-				
U8	US-				
U9	US-				
U10	US-				
U11	US-				
U12	US-				
U13	US-				

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
F1	WO	96/32152	10-17-1996	Inhale Therapeutic Systems	All	
F2	WO	98/16205	04-23-1998	Inhale Therapeutic Systems	All	
F3	WO	00/54797	09-21-2000	Novartis AG	All	
F4	WO	2004/060528	07-22-2004	Aventis Behring, L.L.C.	All	
F5						
F6						
F7						
F8						
F9						

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

<p>Substitute for form 1449/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				<b>Complete if Known</b>	
Sheet	2	of	2	Application Number	10/578,692
				Filing Date	May 10, 2006
				First Named Inventor	Rajiv Nayar
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
				Attorney Docket Number	GJE-7462CXC1

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	R1	VEMURI, S. et al., "Effect of Cryoprotectants on Freezing, Lyophilization, and Storage of Lyophilized Recombinant Alpha <sub>1</sub> -antitrypsin Formulations," <i>PDA Journal of Pharmaceutical Science and Technology</i> , 1994, pages 241-246, Vol. 48, No. 5.		
	R2			
	R3			
	R4			
	R5			
	R6			
	R7			
	R8			
	R9			
	R10			

Examiner Signature	Date Considered
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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